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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,604	02/08/2002	Felix Franks	0022.11	2751

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NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/27/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,604

Applicant(s)

FRANKS ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,17-21,24-27,29,30 and 32-38 is/are rejected.
- 7) ☒ Claim(s) 16,22,23,28 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 31, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-14 have been cancelled.
3. Claims 15-38 have been added and are examined on the merits.

Terminal Disclaimer

The terminal disclaimer filed on March 31, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. Nos. 5,928,469, and 6,071,428 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claims 16, 22, 23, 28, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

4. Claims 15, 17-20, 24-27, 29, 32, 33, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Beek et al. (Neth. Milk Dairy Journal (1969) Vol. 23, pp. 46-54) in light of Roos Carbohydrate Research, (1993) vol. 238, pp. 39-48) and European Patent Application No. 0 383 569, as evidence of inherency for the reasons set forth in the previous Office action.

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All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that rennin is not a therapeutic protein. However, rennin is used as a dietary supplement to help digest dairy products.

Applicant also argues that the spray-dried composition of van de Beek would not inherently be in a glassy state because spray drying does not necessarily result in the formation of a glassy state because the formation of the glassy state depends on many different factors such as percent moisture, number, types, and amounts of components in the mixture, spray drying condition, and the tendency of the excipients towards crystallization. Applicant provides references that show that sucrose and lactose tend towards crystallization. Applicant also argues that the composition of van de Beek would not necessarily have the claimed glass transition temperatures.

However, these arguments by applicant are not persuasive. Van de Beek clearly teaches preserving enzymes by spray drying the enzymes with sucrose or lactose. Van de Beek teaches spray-drying the same active material together with the same carrier substance as claimed by applicant in the anticipated claims. Since van de Beek follows the exact process for making a composition with the same ingredients as applicant's claim, the composition of van de Beek would have to be in a glassy state and have the correct glass transition temperatures if applicant's invention functions as claimed. Therefore, applicant's arguments regarding the uncertainty of glass formation and transition temperature are not persuasive because van de Beek is creating a spray-dried particle that is of the same composition as that of applicant. Thus, van de Beek's particle must be in a glassy state and have the same glass transition temperatures because a composition that is identical in composition to applicant's and is processed in the same manner

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as claimed must be the same as applicant's claimed composition if applicant's invention is operable as currently claimed.

5. Claims 15, 17-20, 24-27, 29, and 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Okura Seiyaku (Abstract - Japanese Patents Gazette - Week 8604 - Section Chemical - J6 0244-288 A (1988)) (referred hereafter as "Okura") for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the spray-dried composition of Okura would not inherently be in a glassy state because spray drying does not necessarily result in the formation of a glassy state because the formation of the glassy state depends on many different factors such as percent moisture, number, types, and amounts of components in the mixture, spray drying condition, and the tendency of the excipients towards crystallization. Applicant provides references that show that mannitol tend towards crystallization. Applicant also argues that the composition of Okura would not necessarily have the claimed glass transition temperatures.

However, these arguments by applicant are not persuasive. Okura clearly teaches preserving enzymes by spray drying the enzymes with lactose, mannitol, dextran, or dextrin. Okura teaches spray-drying the same active material together with the same carrier substance as claimed by applicant in the anticipated claims. Since Okura follows the exact process for making a composition with the same ingredients as applicant's claim, the composition of Okura would have to be in a glassy state and have the correct glass transition temperatures if applicant's invention functions as claimed. Therefore, applicant's arguments regarding the uncertainty of

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glass formation and transition temperature are not persuasive because Okura is creating a spray-dried particle that is of the same composition as that of applicant. Thus, Okura's particle must be in a glassy state and have the same glass transition temperatures because a composition that is identical in composition to applicant's and is processed in the same manner as claimed must be the same as applicant's claimed composition if applicant's invention is operable as currently claimed.

6. Claims 15, 17-21, 24-27, 29-30, 32-38 are rejected under 35 U.S.C. 102(b) as being anticipated by 3,202,731 in light of Klech et al. (Journal of Pharmaceutical Sciences (1990), Vol. 79, pp. 999-1004), as evidence of inherency for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '731 does not teach the claimed invention because the reference does not teach drying atomized droplets by passing the mixture through a heated gas stream. However, the reference atomizes the mixture of active substance and carrier using a heated gas stream. The temperature of the gas stream is 50 to 100 degrees Celsius (see claim 1). In addition, applicant argues that the reference does not teach drying the mixture to form a powder that has a moisture content of 3 to 9% by weight. However, this limitation is stated to be an optional limitation in claim 15; therefore, the reference is still considered to anticipate the stated claims.

7. No claims are allowed. However, claims 16, 22, 23, 28, and 31 would be allowable if amended to overcome the above claim objection.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
June 26, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER